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TITLE: Post Admission Cognitive Therapy (PACT) for the Inpatient Treatment of Military Personnel with Suicidal Behaviors: A Multi-Site Randomized Controlled Trial

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14. ABSTRACT The broad objective of this study is to evaluate the efficacy of a cognitive behavioral intervention, titled, <i>Post Admission Cognitive Therapy (PACT)</i> , for military personnel psychiatrically hospitalized, with either a recent or a lifetime suicide attempt. The research design is a multi-site, single-blind, randomized controlled trial (RCT). A total of 218 individuals who are over the age of 18, English speaking, and willing to provide informed consent will be recruited from the inpatient psychiatric units at the Walter Reed National Military Medical Center and the Fort Belvoir Community Hospital. Participants will be randomized into one of two conditions: (1) [Post Admission Cognitive Therapy (PACT) + Enhanced Usual Care (EUC)] or (2) Enhanced Usual Care (EUC). Individuals randomized into PACT+EUC will participate in the study assessments, receive six 60-90 minute individual face-to-face PACT sessions provided during their inpatient stay, up to a maximum of four 60-minute phone PACT booster sessions during the 3 months post hospital discharge, and case management for 12 months. Individuals randomized into the control condition (EUC) will not receive the study intervention; they will receive the usual care provided in the inpatient setting, participate in study assessments, and receive case management services for 12 months. Patients in both conditions will be assessed on the dependent measures at baseline and at 1-, 3-, 6-, and 12-months. Delivering a brief intervention during hospitalization, followed by an aftercare component, targets individuals at high risk for future suicide, specifically young, psychiatrically hospitalized adults under the direct stress of a military career.				
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Introduction

Background: Suicide remains a serious national public health problem and has become a leading cause of death in the United States military. To date, there is no evidence-based civilian or military inpatient interventions aimed at the reduction of suicide behavior. Our proposal addresses this important gap and aims to evaluate an innovative suicide intervention, *Post-Admission Cognitive Therapy* (PACT). Left untreated, severe suicide ideation and/or suicide attempts that require psychiatric hospitalization may place an individual at a lifetime risk for increased psychopathology, subsequent suicide behavior, and death.

Objective: The broad objective of the proposed study is to empirically evaluate the efficacy of a cognitive behavioral intervention, titled, *Post-Admission Cognitive Therapy (PACT)*, for military service members psychiatrically admitted for inpatient care due to a suicide-related event with either a recent or a lifetime suicide attempt.

Specific Aims: To evaluate the efficacy of PACT plus Enhanced Usual Care (EUC) versus EUC for the prevention of suicide in psychiatrically hospitalized military personnel at follow-up (1, 3, 6, and 12-month) on (1) incidence of repeat suicide attempt(s) and number of days until a repeat suicide attempt (primary outcomes), and (2) psychiatric symptoms (depression, trauma, sleep, suicide ideation), repeat number of psychiatric hospitalization(s), hope for one's future, and acceptability of treatment (as measured by time to linkage to specialty care, attitudes toward seeking help for mental health issues, and subsequent mental health service utilization) (secondary outcomes). We expect that adults in the PACT+EUC (experimental) condition compared to those in the EUC (control) condition will show favorable outcomes on both primary and secondary measures.

Study Design: The research design is a multi-site, single-blind, randomized controlled trial (RCT). A total of 218 individuals who are over the age of 18, able to communicate in English and willing to provide informed consent will be recruited from the inpatient psychiatric units at Walter Reed National Military Medical Center (WRNMMC) and Fort Belvoir Community Hospital (FBCH). Participants will be randomized into one of two conditions: (1) [Post Admission Cognitive Therapy (PACT) + Enhanced Usual Care (EUC)] or (2) Enhanced Usual Care (EUC). Individuals randomized into PACT+EUC will participate in the study assessments, receive six 60-90 minute individual face-to-face PACT psychotherapy sessions provided during their inpatient stay, up to a maximum of four 60-minute phone PACT booster sessions during the 3 months post hospital discharge, and case management services for 12 months. Individuals randomized into the control condition (EUC) will not receive the study intervention; they will receive the usual care provided in the inpatient setting, participate in study assessments, and receive case management services for 12 months. Patients in both conditions will be assessed on the dependent measures at baseline and at 1, 3, 6, and 12-month follow-up intervals.

Relevance: Delivering a brief and possibly potent psychotherapeutic intervention during a psychiatric inpatient hospitalization followed by an aftercare component aims to directly target individuals at high risk for future suicide behavior, specifically young, psychiatrically hospitalized adults under the direct stress of a military career. The development and empirical validation of an inpatient cognitive behavioral treatment is a significant endeavor in our national as well as Department of Defense (DoD) suicide prevention efforts. If *Post-Admission Cognitive Therapy* is found to be efficacious, the intervention can be subsequently disseminated to inpatient settings as the standard of care for military personnel admitted for suicide-related events.

Body

During each quarter of the past year, we engaged in the following activities: (1) working directly with the Henry Jackson Foundation (HJF) to ensure the timely processing of the sub-awards and contracts for the study (Duke University; KAI, Inc.; and University of Michigan); (2) working directly with the regulatory boards at the Uniformed Services University of the Health Sciences (USUHS), Walter Reed National Military Medical Center (WRNMMC), Ft. Belvoir Community Hospital (FBCH), Duke University IRB, Michigan University IRB, and the Human Research Protections Office (HRPO) at the USAMRMC Office of Research Protections to prepare all required IRB-related documentation; (3) continuing the process of new employee selection and recruitment; (4) providing training to newly hired staff; (5) coordinating with various study collaborators on research efforts; (6) purchasing study-related materials and supplies; (7) refining the baseline and follow-up assessment protocols, standard operating procedures, and treatment protocols; (8) maintaining regular contact with collaborators; (9) working with the KAI team to refine electronic study related forms and questionnaires, problem-solve study-related challenges, and track adverse events; (10) continuing with recruitment of study participants at both study sites; (11) conducting follow-up phone and web-based assessments; and (12) offering study case management for the multi-site RCT.

Overview of Study Activities for Quarters 1-4

Performance Period: February 1, 2014 to January 31, 2015

Below is a list of the tasks we have made progress on during Year 4. These tasks correspond to the Statement of Work, Years 1-4. More detail about each task is provided below.

- ✓ Schedule regular conference calls for key study collaborators
- ✓ Submit appropriate IRB applications for Site 1 (WRNMMC) and Site 2 (FBCH) study implementation
- ✓ Interview, select, and hire qualified study personnel for both implementation sites
- ✓ Develop study forms, database/randomization, risk management guide, and regulatory binders
- ✓ Prepare final version of adherence rating forms
- ✓ Conduct competency and adherence ratings
- ✓ Conduct training seminars for study assessment and treatment procedures
- ✓ Continue with recruitment of study participants at both study sites
- ✓ Conduct follow-up phone and web-based assessments
- ✓ Offer study case management
- ✓ Attempt to meet a “set” recruitment goal
- ✓ Setup annual meetings for study collaborators
- ✓ Hold DSMB annual meetings
- ✓ Prepare and submit all applicable quarterly and annual reports

Scheduled regular conference calls for key study collaborators

The PI of the study, Dr. Marjan Holloway, along with the study Coordinator, Dr. Laura Neely held regular meetings with Dr. David Goldston and Dr. Cheryl King on a bi-weekly basis for 1 hour. These meetings were used to discuss implementation challenges, methodology issues, and

risk management/adverse event reporting. Meeting minutes were recorded for each conference call to document decisions made.

Submitted appropriate IRB applications for Sites 1 & 2

On September 12, 2014, continuing review packages were submitted to (a) the WRNMMC Lead site, (b) the WRNMMC Local recruitment site, and (c) the FBCH Local recruitment site. In addition to the required continuing review documents, the submissions included a minor amendment to change the roles of three research personnel. Each site received approval on September 25, 2014. The continuing review was then submitted to the USUHS IRB for secondary concurrence on September 26, 2014 and approval was received on October 8, 2014. The continuing review was submitted to HRPO on October 22, 2014 and approval was received on November 10, 2014. We also received publication clearance from WRNMMC for 3 publications during the current reporting period.

Interviewed, selected, and hired qualified study personnel for both implementation sites

During Year 4, we have had frequent staff turnover of research assistants. Several research assistants left for various reasons, including moving on to internship placement to complete doctoral program requirements. We held several rounds of interviews looking for highly qualified applicants who could fill the open positions. These individuals would provide consenting coverage, case management, and data management. We hired three Bachelor's level research assistants, Ms. Victoria Colborn, Ms. Kate Caffery, and Ms. Margaret Baer, to provide case management at both sites. We also hired one master's level research assistant, Ms. Joy Browne, to assist with data collection, clean-up, and analysis. We held several interviews to find an additional postdoctoral fellow to implement the PACT treatment. After an exhaustive search, we hired Dr. Stacy Tylor (with experience in working with military patients), who will provide weekend coverage for the PACT intervention.

Developed study forms, database/randomization, risk management guide, & regulatory binders

The study forms, database, and randomization have been finalized. Ms. Kanchana Perera, biostatistician, maintains regular contact with KAI to refine the study forms and database. Mr. Robert Wheeler, IRB Coordinator, has finalized the regulatory binder. He has gathered all necessary documents and has created an electronic copy accessible to all lab members. He continues to maintain and update the regulatory binder as needed.

Prepared final version of adherence rating forms & conducted review of competency and adherence ratings

The research team is actively working on modifying the Cognitive Therapy Rating Scale for the purposes of PACT. This will then be used while listening to approximately 10% of the cases to ensure fidelity and integrity of the treatment protocol. We hope to have this finalized in the next reporting period.

Conducted training seminars for study assessment and treatment procedures

The following list outlines weekly or biweekly trainings held throughout the year on a regular basis.

- Each case manager receives weekly individualized training on Consenting Procedures

and Case Management from a doctoral level clinician

- Supervision for research personnel is held weekly for 1-2 hours to discuss cases and the implementation of various aspects of the PACT RCT
- Group supervision for clinical personnel is held weekly for 1-2 hours to discuss cases and the application of the PACT intervention delivery, supervised by licensed psychologists
- USUHS Study Clinicians participate in weekly 1-hour booster session supervision with Dr. Cheryl King and Dr. Steve Chermack from the University of Michigan, via conference call

Continued with recruitment of study participants at both study sites

We have continued with recruitment of study participants at both study sites, WRNMMC and FBCH. To date we have randomized 39 study participants (excluding pilot cases). Please see Appendix B CONSORT diagram for more information on recruitment.

Conducted follow-up phone and web-based assessments

The Duke assessors continue to conduct follow-up phone assessments. Any issues with implementation or data entry were problem-solved during conference calls with the USUHS and KAI team. The assessors were trained on entering data via the web, on the risk management SOP for the study, on how to reconcile missing or incorrect data, on the Baseline Assessment Clinical Summary report, and on military culture. For more detailed information on follow-up activities, please refer to Appendix B CONSORT diagram for the overall study.

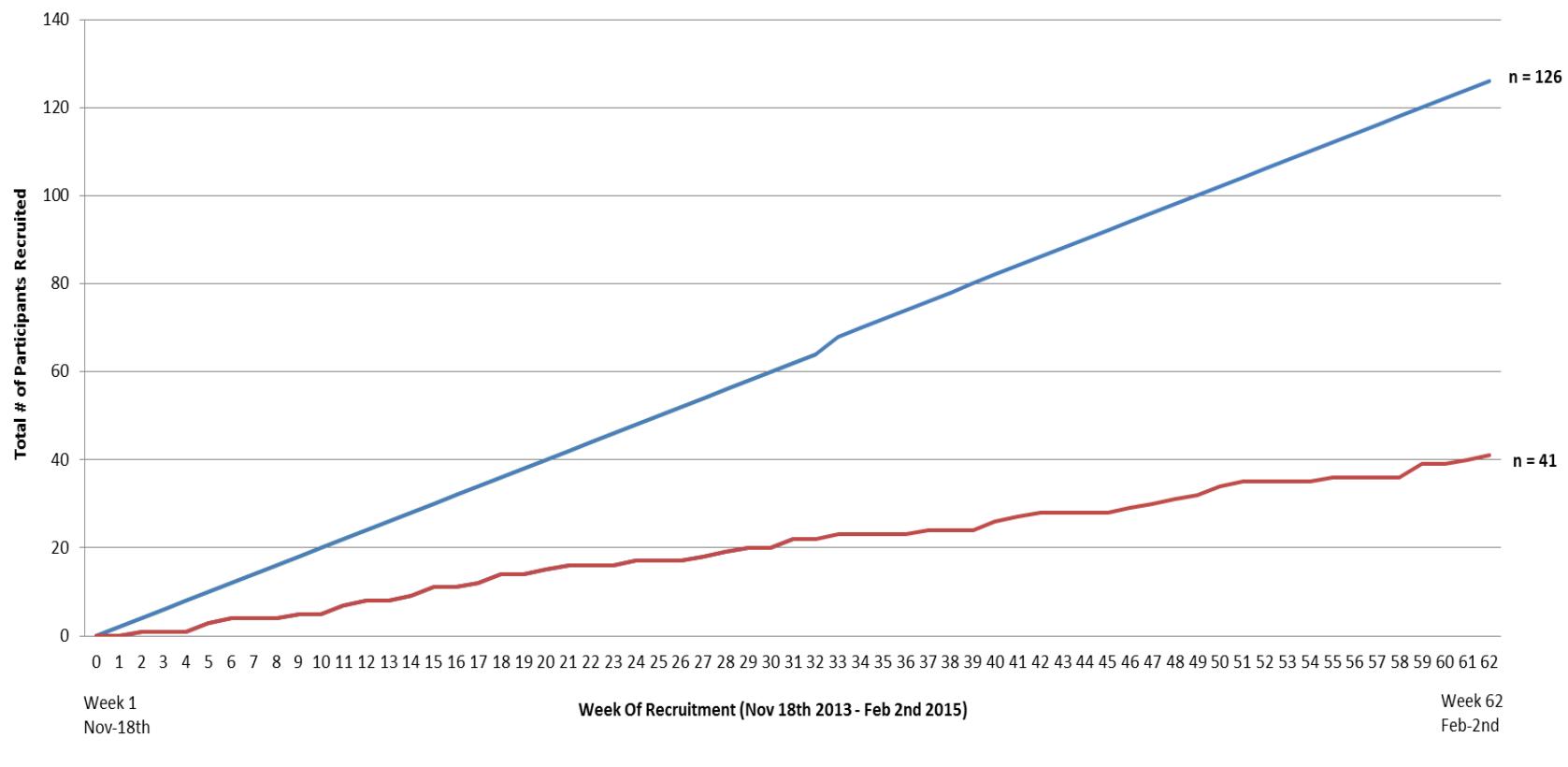
Offered study case management

Case managers continue to provide case management for study participants. Challenges were problem-solved during a weekly PACT Team Meeting and on an individual basis during supervision with a doctoral level clinician.

Attempted to meet a “set” recruitment goal

Due to unforeseen obstacles and challenges, such as shorter length of inpatient stay, we have not met our recruitment goal. Please see Figure 1 below, which displays the rate of recruitment, projected vs. actual.

Figure 1: Projected Recruitment (blue), and Actual Recruitment (red)



Current Recruitment Strategies

Morning Report Attendance: A member of our research team participates in the morning report meeting at each site on a daily basis. The morning report meeting includes all attending physicians, residents, and interns, and provides updates on current patients and a brief case history of new admissions to the unit. Morning report is the primary source of information for eligible participants. The morning report manager uses this time to meet with the potential research participant's attending physician or resident to request permission for approaching patients. During recent months, there has been increasing difficulty connecting with providers. At WRNMMC, providers often have staff-only meetings immediately following morning report which excludes the morning report manager. We have made efforts to connect with providers via phone or email, but continue to struggle with ensuring timely and effective communication given their demanding schedules.

Research Liaison: In addition to morning report attendance at FBCH, we have a current FBCH staff member who acts as a liaison between the morning report manager and the attending physicians or residents. Her primary role on our project is to ensure that the physician or resident is made aware of potential patients and to coordinate communication between our research team and FBCH staff members. Unfortunately, we have lost a similar staff member at WRNMMC who left her position several months ago due to termination of her position.

Provider Recruitment Education: The PI (Dr. Holloway), the Morning Report Manager, and key research personnel have presented an overview of the study at both WRNMMC and FBCH morning report. This presentation was provided for the exiting providers, new residents, and psychiatry support staff. During this meeting, information on the research study, eligibility criteria, and the procedures associated with patient referral and recruitment were discussed. This strategy was previously employed during the pilot studies and has proven to be an effective means of increasing enthusiasm and cooperation from the inpatient psychiatry staff, especially given the frequent turnovers. Furthermore, our morning report manager at WRNMMC has noticed that there appears to be a great deal of confusion about the "permission to approach process," where providers aim to get permission for participation from the patient as opposed to simply asking for permission for our staff member to approach him or her to discuss the study. We were able to clarify this process during our meeting and answer any questions posed by the psychiatry staff.

Expand Subject Population: We have modified the study subject population criteria to include dependents over the age of 18. We believe this strategy will increase the number of potential patients as well as enhance the generalizability of the research findings. We have submitted an amendment to the IRB and hope to have approval in the next reporting period.

Modify inclusion criteria: We have modified the study inclusion criteria such that service members admitted for suicide ideation can be enrolled into the study. We have submitted an amendment to the IRB and hope to have approval in the next reporting period.

Options Under Consideration for Increasing Recruitment Rate

Add site for recruitment: We are currently considering adding one additional research sites. We have consulted with the site PIs at WRNMMC and FCBH, COL Grammer and Dr. Weaver, to

request site suggestions. At this time, we are first pursuing the possibility of adding the Washington DC Veterans Medical Center as a third study site.

Setup annual meetings for study collaborators

Scheduling for the annual meeting for study collaborators has been discussed on the bi-weekly conference call between Dr. Holloway, Dr. Goldston, and Dr. King. The decision was made that an annual meeting is not be needed, as regular communication is held on a bi-weekly basis, and that the time and funds may be better utilized for other aspects of the study.

Held DSMB annual meetings

During Quarter 1, the USUHS research team formulated a DSMB report and sent it to the DSMB members on February 24, 2014. After waiting several months for a response, the USUHS research team sent a second updated DSMB report on July 11, 2014. The DSMB reviewed the report, the preliminary data, and the adverse event log. On July 17, 2014 we received a response from Dr. Kate Comtois, DSMB Chair: "The DSMB has reviewed your report and adverse events and approves you to proceed without a meeting. We have no concerns on adverse events or safety but strongly encourage you to try all recruitment avenues and we agree with your ideas."

The DSMB requested another email update to be sent in November, 2014. On November 18, 2014, the USUHS research team sent 1) CONSORT diagram, 2) rate of recruitment, 3) adverse event report, and 4) data tables to all three DSMB members. On November 22, 2014, we received a response from Dr. Kate Comtois, DSMB Chair: "I have reviewed your report with the other DSMB members and we concur that your project can proceed without a meeting. While we noted the higher number of SAEs for one condition, we agreed that the numbers are too small to base conclusions upon. We will continue to watch this over future reports. We do not see a DSMB role in your potential recruitment strategies at this time as they do not appear to affect participant safety. Please proceed as your group sees fit. However, if you are considering a strategy that would increase risk, please let the DSMB review it before implementation. We look forward to hearing about your progress in our next report July 2015."

The next full meeting will be held in July, 2015.

Prepared and submitted all applicable quarterly and annual reports

During Year 4, all quarterly reports were submitted on time to the sponsor. Please note that Quarter 2 quarterly report was waived due to the In Progress Review meeting.

Additional Study-Related Activities

Amendment Submission

An amendment was submitted to the WRNMMC IRB on December 12, 2014. In this amendment, we made the following changes:

1. changes in personnel names and responsibility descriptions;
2. minor changes to the protocol language to present a more polished and concise document;

3. changes to the study inclusion criteria such that we can broaden our recruitment criteria for increased enrollment and overall generalizability;
4. change in procedures following consenting of study participants such that our team can selectively include patients with higher severities of suicide ideation;
5. change in randomization procedures given the inclusion of individuals with suicide ideation without suicide attempt history
6. increase in study sample size given the change in study screening;
7. addition of two study questionnaires; and
8. change of study end date from April 30, 2017 to March 1, 2018

The submission went through an administrative pre-review and several modifications were requested. These modifications were addressed by study staff and, at the end of the current reporting period; the package was ready for re-submission. We will report further on this amendment in the Year 5, Quarter 1 report.

Regulatory Summary and IRB Audit

Over the past year, we have been diligently managing regulatory documentation for all of our studies. For this study, with guidance from the WRNMMC IRB, we have created and continue to maintain an electronic version of the regulatory binder. In addition, we have conducted internal monitoring of our studies to ensure that all regulatory documentation is maintained in compliance with requirements of all oversight organizations.

On March 27, 2014, the FBCH Performance Site regulatory files underwent an audit by the Army Human Protections Office (AHRPO) / Clinical Investigation Regulatory Office (CIRO) / Research Regulatory Oversight Office (R2O2). This audit was part of a larger audit of the WRNMMC IRB. The auditor remarked that she was impressed with our regulatory compliance and organization. She provided a few suggestions for better practices, which she clearly labeled as only suggestions, not requirements. On September 12, 2014, we received written feedback, a detailed report of the Army Human Research Protections Office (AHRPO) and OUSD (P&R) Research Regulatory Office (R2O2) Assessment of FBCH Human Research Protections Program. There were several notable positive remarks including "This was a model for organization and segregation of data" and "Recommend using this study as a model for training or benchmarking."

Implementation at Site 2: Fort Belvoir Community Hospital

The USUHS research team was informed by Mr. Christopher Forte, Health System Specialist at FBCH, that FBCH requires a higher level security clearance than what is needed at WRNMMC. This process has been tedious and very time consuming as we have had to tackle issues related to credentialing, time keeping for our hours based on the FBCH system, security clearances, and occupational health requirements. Given that our study staff members are government contractors serving in the role of researchers, we collaboratively worked with FBCH staff to best get our study up and running – and our staff functional per hospital guidelines.

On September 5, 2014, Dr. Marjan Holloway and Dr. Laura Neely met with LTC Ann Marie Nayback-Beebe, Director of the FBCH IRB, to discuss the in-processing procedure at FBCH and problem-solve some of the challenges outlined above. We came to an agreement on what would be required, such as only Day 1 of the hospital orientation training and occupational health

prerequisites, and what would not be required, such as reporting time worked in the FBCH system, DMHRSi. LTC Nayback-Beebe offered to relay this information to Mr. Christopher Forte. Since the meeting the in-processing of our staff has been more streamlined. Our staff made in-processing at FBCH a top priority, and completed all required paperwork, trainings, orientations, and clearances. We have three clinicians and one case manager approved to see patients on the inpatient psychiatry unit.

Implementation at Possible Site 3: Washington DC VA Medical Center

We have held regular conference calls with Dr. Maria Llorente, possible site PI, and Dr. Barbara Schwartz, potential collaborator. Dr. Schwartz is assisting in preparing the IRB application, to add the DC VA as a third site. We have created a team of research personnel to assist in the IRB application for WRNMMC, USUHS, and HRPO. Dr. Laura Neely, study coordinator, has begun the lengthy process of becoming a credentialed provider at the DC VA. She has also simultaneously worked on the Without Compensation (WOC) appointment application. She hopes to have this completed in the next quarter. Once she has completed this process, she will be able to supervise the two post-doctoral fellows when providing PACT at the DC VA.

Development of a PACT Therapy Workbook and Treatment Guide

The USUHS research team has worked on developing a “Therapy Workbook” for participants. This consists of handouts and supporting documents that will assist the clinician and participant during the PACT treatment delivery. Our goal is to have this published as an addendum to the PACT Treatment Guide, which is also in development.

Attended WRNMMC IRB Research Round Table meetings

The WRNMMC IRB Research Round Table Meeting is sponsored by the WRNMMC IRB and the time is used to provide updates on any changes to the IRB or submission process and to answer any questions. Attendance is prioritized to maintain a relationship with the WRNMMC IRB and to ask pertinent questions to the functioning of our research study. Important updates are shared with the research team and incorporated into the infrastructure and regulatory binders. A member of the research team attended each monthly WRNMMC IRB Research Round Table meeting during the past year.

Preparation of Memorandum of Understanding (MOU)

The WRNMMC IRB had informed us that the CRADA submitted before the BRAC was null and void. The Study Coordinator (Dr. Neely) spoke with Mr. Alan Cash in the Office of Research and Technology Applications at WRNMMC on April 30, 2013 and confirmed that a CRADA is not needed for this study. Mr. Cash formulated an MOU (between USUHS, WRNMMC, & FBCH) and forwarded it to USUHS to be approved. The USUHS Agreements Office (Ms. Malika Graham), USUHS legal counsel (Mr. Josh Girton), FBCH legal counsel (Mr. John Konst), and WRNMMC legal counsel (Ms. Dina Bernstein) all have reviewed and approved the MOU. On September 15, 2014, CAPT Jennifer Vedral-Baron, Director of FBCH, signed the document. It has been forwarded to WRNMMC for signature. Dr. Laura Neely, study coordinator, has maintained regular contact with Mr. Steven Ross, Grants Manager, Department of Research Programs, WRNMMC to obtain regular updates on the MOU signature status. We hope to obtain the WRNMMC director's signature by next quarter, so that we may forward to USUHS to finalize.

Maintained contact with the study medical monitor

Contact with the study Medical Monitor, Dr. Russell Carr is maintained via email and IRBNet as well as by phone as needed. Dr. Carr has kindly agreed to serve as the Medical Monitor for both sites, WRNMMC and FBCH.

Obtained NIH Certificate of Confidentiality

On June 16, 2014, the National Institutes of Health issued a Certificate of Confidentiality for our study. NIH has requested several edits to the consent form. We have incorporated the edits and submitted to the WRNMMC IRB as part of the latest amendment. We hope to have this approved during the next quarter.

Participated in the In-Progress Review (IPR)

The study was presented at the IPR annual meeting held in May, 2014. This provided an opportunity to exchange ideas with other investigators involved in military suicide prevention research and to problem-solve implementation and recruitment challenges.

PACT Study Communications

We attempted to set up a study-specific email address, with a “no-reply” function, to email participants reminders of case management, therapy, and follow-up phone appointments. We have tried to work with the WRNMMC, USUHS, and HJF IT departments to get this set up, however we have experienced several obstacles which appear to be insurmountable. We have now turned our attention to developing a study “post card” to thank participants for their involvement in the study, and to remind them of upcoming follow-up appointments. We hope to have this finalized in the next quarter.

Site Specific Reports of Activities in Collaboration with USUHS Team

KAI Research, Inc.
Progress Report - Contract Number: 721296
November 1, 2014 – January 31, 2015

A. Introduction – Contract Primary Objectives and Tasks

KAI Research, Inc. (KAI), as the Data and Statistical Coordinating Center (DSCC) is responsible for providing coordination, data management, monitoring, and logistical support for the PACT study.

B. Brief Narrative of Tasks Accomplished

KAI accomplished the following activities:

- 1. Database Revisions** – As requested the following revisions were implemented in the database in July:
 - Case Manager Contact Form- revised the edits so they would run properly and scheduled two more copies of this form in the Discharge Visit
 - Study Therapy Tracking Form- revised the edits to ensure the proper completion of the form
 - Cornell Services Index- added an additional question regarding participating in other research studies
 - SSI- added an unknown checkbox next to the date field
 - Created a new eCRF called Comments for entering a patient narrative that will be added to the Baseline Clinical Summary Report
- 2. Reports**
 - Sent the CONSORT data report and the Baseline Measures report to USUHS monthly at the end of each month.
 - Added the “patient narrative” field to the Baseline Clinical Summary Report.
- 3. Data Management** – Worked with the Duke staff in facilitating their access to the database via Citrix which should eliminate the java compatibility issues the Duke team experienced.
- 4. Database Access** – Trained 2 new USUHS users, Margaret Baer and Joy Browne on the database on 1/22.
- 5. IVRS** – Added three new USUHS users to the IVRS randomization email and removed one who had left.
- 6. Project Management** - Celeste Crouse, the KAI project manager, performed the following duties: served as the first line of contact for USUHS, supervised the entire KAI study team, and ensured that all deliverables to date were provided on time and of the highest quality.

University of Michigan (Site PI: Cheryl King, Ph.D.)

1. Contribute to the development of case management protocol, including dose (amount) and duration of case management to be offered to all study participants in both treatment arms.
2. Develop draft versions of fidelity assessment tools for review at PACT Grant meeting with project leadership. These involved: (a) group meetings with University of Michigan team to discuss and fine-tune protocol and associated documents; (b) conference calls with project leadership to discuss feedback and incorporate input.
3. Develop draft plan for provision of clinical training to therapists who will implement PACT telephone booster sessions, including in-person training and plan for fidelity assessment and follow-up supervision/consultation.
4. Participate in project conference calls with PI, Marjan Holloway, Ph.D., Co-PI, David Goldston, Ph.D., and key members of study team to discuss IRB applications, the timeline and plan for piloting telephone booster sessions, and a wide range of study issues.
5. Provide ongoing supervision for telephone booster sessions for participants randomized to the treatment condition.

Duke University (Site PI: David Goldston, Ph.D.)

Grant activities at Duke University during the past year include:

1. Participate in PACT project conference calls with project leadership regarding the PACT inpatient protocol, aftercare protocol, safety protocol, assessment protocol, and outcomes.
2. Discuss and provided feedback on follow-up protocols.
3. Review and provided feedback for KAI computerized study forms.
4. Complete training for follow-up assessors regarding assessment instruments and protocol for contacts with participants.
5. Complete follow-up assessments for randomized participants
6. Monitor adverse events occurring during follow-up and follow Duke and WRNMMC guidelines for reporting.
7. Problem-solve any assessment and clinical implementation challenges.

Denver VA (Site PI: Lisa Brenner, Ph.D.)

The PI has held a phone meeting with Dr. Lisa Brenner. Given that the study has faced a late start and the relatively low number of TBI patients in the study, we have made the decision to stop this subaward and instead request from the sponsor to utilize the remaining funds on this subaward for other study related expenses – i.e., plans for a no cost extension. Dr. Brenner has kindly offered to stay involved in this study and serve as a consultant on TBI patients who get enrolled in the study.

Key Research Accomplishments

The key research accomplishments over the past year include the following:

- Receipt of regulatory approvals on the study protocol from various boards
- Finalization of the study baseline and follow-up assessment battery and procedures
- Manualized drafts of study intervention, case management, and risk management SOPs
- Creation of study web-based electronic forms and database
- Training of personnel on assessment and intervention procedures
- Problem solving of implementation challenges and plans to add 3rd recruitment site
- Dissemination of information about PACT via national and international presentations

Given the magnitude of the public health problem of military suicide and the increasing rates of psychiatric hospitalizations within DoD, the development and empirical validation of an inpatient cognitive behavioral treatment is a significant suicide prevention endeavor.

Delivering a brief and possibly potent psychotherapeutic intervention during a psychiatric inpatient hospitalization followed by an aftercare component aims to directly target individuals at high risk for future suicide behavior, specifically young, psychiatrically hospitalized adults under the direct stress of a military career.

Reportable Outcomes

Section I. Manuscripts, Abstracts, Presentations

Peer Reviewed Manuscripts

1. Ghahramanlou-Holloway, M., Cox, D., & Greene, F. (2012). Post-admission cognitive therapy: A brief intervention for psychiatric inpatients admitted after a suicide attempt. *Cognitive and Behavioral Practice*, 19, 233-244.
2. Neely, L.L., Irwin, K., Carreno Ponce, J. T., Perera, K., Grammer, G., & Ghahramanlou- Holloway, M. (2013). Post Admission Cognitive Therapy (PACT) for the prevention of suicide in military personnel with histories of trauma: Treatment development and case example. *Clinical Case Studies*, 12(6), 457-473.
3. Gharamanlou-Holloway, M., Tucker, J., Neely, L. L., Carreno-Ponce, J. T., Ryan, K., Holloway, K., & George, B. (2014). Suicide risk among military women. *Psychiatric Annals*, 44(4), 189-193.
4. Kochanski-Ruscio, K. M., Carreno-Ponce, J. T., DeYoung, K., Grammer, G., & Ghahramanlou-Holloway, M. (2014). Diagnostic and psychosocial differences in psychiatrically hospitalized military service members with single versus multiple suicide attempts. *Comprehensive Psychiatry*, 55, 450-456.
5. Ghahramanlou-Holloway, M., Neely, L., & Tucker, J. (2014). A cognitive-behavioral strategy for preventing suicide. *Current Psychiatry*, 13(8), 18-25.
6. Ghahramanlou-Holloway, M., Brown, G. K., Currier, G. W., Brenner, L., Knox, K. L., Grammer, G., Carreno-Ponce, J. T., & Stanley, B. (2014). Safety Planning for Military (SAFE MIL): Rationale, design, and safety considerations of a randomized controlled trial to reduce suicide risk among psychiatric inpatients. *Contemporary Clinical Trials*, 39(1), 113-123.
7. Neely, L. L., Tucker, J., Carreno, J. T., Grammer, G., & Ghahramanlou-Holloway, M. (2014). Suicide Risk Assessment and Management Guidance for Military Psychologists. *The Military Psychologist*, 29(3), 18-21.
8. Greene, F., Wagner, B., Neely, L. L., Cox, D. W., Kochanski, K., Perera, K. U., & Ghahramanlou-Holloway, M. (in press). How parental reactions change in response to adolescent suicide attempt. *Archives of Suicide Research*.

Treatment Guide

1. United States Air Force Medical Operations Agency. (2013). *Air Force guide for suicide risk assessment, management, and treatment*. San Antonio, Texas.

Invited Book Chapters

1. Ghahramanlou-Holloway, M., & Bakalar, J. (2013). Treating Veterans and military families. In G. P. Koocher, J. Norcross, & B. Greene (Eds.), Psychologists' desk reference: Third edition. New York: Oxford University Press.
2. Ghahramanlou-Holloway, M., Branlund, S., Neely, L. L. (2014). Deployment-related factors, mental health, and suicidal self-directed violence. In C. Dobre (Ed.), Psihologia Militara, ISBN 978-606-660-110-8. Bucharest: Editura Universitatii Nationala de Aparare.
3. Ghahramanlou-Holloway, M., Neely, L.L., & Tucker, J. (in press). Treating suicide risk in inpatient settings. In C. J. Bryan (Ed.), A guide to brief cognitive behavioral treatments for suicide risk across clinical settings. New York: Routledge.
4. Ghahramanlou-Holloway, M., Garrick, J., & Carreno-Ponce, J. T. (in press). Suicide-related ideation and behaviors in military women. In C. Ritchie and A. Naclerio (Eds.), Women at war: Medical and psychological issues. New York: Oxford University Press.
5. Koss, K., Neely, L. L., Tucker, J., VanSickle, M., & Ghahramanlou-Holloway, M. (in press). Impulsivity, problem-solving, and suicide: Assessment and treatment considerations in the context of scientific literature. In M. A. Cyders (Ed.), Psychology of impulsivity: New research. New York: Nova Publications.
6. Ghahramanlou-Holloway, M., Tucker, J. & Neely, L. L. (in press). Post Traumatic Stress Disorder as a risk for suicide. In Comprehensive Guide to Post-Traumatic Stress Disorders. London: Springer.
7. Tucker, J., Neely, L. L., Colborn, V., Tylor, S., Pak, K. & Ghahramanlou-Holloway, M. (in preparation). Effective Psychotherapeutic Interventions for Loneliness and Cultural Considerations for their Implementation. In M. A. Cyders (Ed.), Loneliness: Psychosocial Risk Factors, Prevalence and Impacts on Physical and Emotional Health. New York: Nova Publishers.

Conference Presentation and Published Abstracts - Selected, 2014

Invited Presentations

1. Ghahramanlou-Holloway, M. (2014, February). Cognitive behavior therapy for the prevention of suicide. Invited two day training workshop, University of Arkansas for Medical Sciences, Psychiatric Research Center, Little Rock, AK.
2. Ghahramanlou-Holloway, M. (2014, April). Treatment needs of suicidal military personnel and family members. Invited presentation at 1st Science Roundtable organized by the Military Family Research Institute (MFRI) in partnership with Senator Joe Donnelly's office, Capitol Hill, Washington, DC.
3. Ghahramanlou-Holloway, M. (2014, May). Pilot trial of inpatient cognitive therapy for the prevention of suicide in military personnel with Acute Stress Disorder or

Posttraumatic Stress Disorder. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.

4. Ghahramanlou-Holloway, M. (2014, May). A brief intervention to reduce suicide risk in military service members and Veterans. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.
5. Ghahramanlou-Holloway, M. (2014, May). Post Admission Cognitive Therapy (PACT) for the inpatient treatment of military personnel with suicidal behaviors: A multi-site randomized controlled trial. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.
6. Ghahramanlou-Holloway, M., Brown, G., Stanley, B. (2014, May). Management of suicide-related events during deployment. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.
7. Ghahramanlou-Holloway, M., & Koss, K. R. (2014, June). Behavioral healthcare utilization and career-related impact: Reducing stigma and barriers to care among United States Marine Corps personnel. Invited presentation at the United States Marine Corps Behavioral Health Branch Research Summit.

Conference Presentations and Abstracts

1. Neely, L. L., & Ghahramanlou-Holloway, M. (2014, May). Post Admission Cognitive Therapy (PACT) for the inpatient treatment of military personnel with suicidal behaviors: A multi-site randomized controlled trial. Paper presented at the Annual Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL.
2. VanSickle, M., & Ghahramanlou-Holloway, M. (2014, August). Opinions on suicide and barriers to care in Marine NCOs: Implications for suicide prevention. Paper presented at the Annual Meeting of the American Psychological Association, Washington, DC.
3. VanSickle, M., & Ghahramanlou-Holloway, M. (2014, August). A principal components analysis of the Perceived Barriers to Care measure in a U.S. Marine sample. Poster presented at the Annual Meeting of the American Psychological Association, Washington, DC.
4. Pak, K., Tucker, J., & Ghahramanlou-Holloway, M. (2014, August). Suicide prevention for the U.S. Armed Forces: Literature review, conceptual model, and lessons learned. Paper presented at the Annual Meeting of the American Psychological Association, Washington, DC.
5. Ghahramanlou-Holloway, M., Brown, G., & Stanley, B. (2014, August). Management of suicide-related events during deployment. Paper presented at the Annual Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL.

Preliminary Data

Formal recruitment for the study, at the Walter Reed National Military Medical Center (WRNMMC) and the Fort Belvoir Community Hospital (FBCH), began on November 18, 2013. Prior to this start date (during the months of August to November 2013), a total of 4 participants were recruited as pilot cases.

The Consolidated Standards of Reporting Trials (CONSORT) flow diagram is provided in Appendix B and provides a detailed outline of flow of participants into the trial. From November 18, 2013 to February 2, 2015, a total of 763 individuals were admitted to WRNMMC and FBCH for suicide-related reasons. Of these individuals, 91 (12%) were referred and approached for consent following expressed interest to hear more about the study. A total of 30 out of 91 individuals (33%) declined the invitation to participate. Overall, 6 consented individuals were discharged from the unit prior to randomization, 16 were excluded based on study inclusion criteria, thus only 39 participants were randomized into study conditions. During this 62-week period of open enrollment, the rate of recruitment has been significantly lower than our estimated plan, which was to have 2 participants from all sites per week. Based on the lower than expected recruitment rate, we continue to consider and implement a number of strategies to increase our recruitment numbers.

Conclusion

There are no study findings to report at the present time. The fourth year of the study has continued to heavily focus on the following activities: (1) working directly with the Henry Jackson Foundation (HJF) to ensure the timely processing of the sub-awards and contracts for the study (Duke University; KAI, Inc.; and University of Michigan); (2) working directly with the regulatory boards at USUHS, WRNMMC, FBCH, Duke University IRB, Michigan University IRB, and HRPO to prepare all required IRB-related documentation; (3) continuing the process of new employee selection and recruitment; (4) providing training to newly hired staff; (5) coordinating with various study collaborators on research efforts; (6) purchasing study-related materials and supplies; (7) refining the baseline and follow-up assessment protocols, standard operating procedures, and treatment protocols; (8) maintaining regular contact with collaborators; (9) working with the KAI team to refine electronic study related forms and questionnaires, problem-solving study-related challenges, and planning for the adverse event reporting/tracking; (10) continuing with recruitment of study participants at both study sites; (11) conducting follow-up phone and web-based assessments; and (12) offering study case management for the multi-site RCT.

The early study conclusions are that at least 12-18 months need to be devoted to obtaining regulatory approvals for research pertaining to suicidal individuals receiving treatment at a military treatment facility. In addition, credentialing issues at various military treatment facilities such as WRNMMC and FBCH for research personnel appear to remain unclear and present unique implementation and financial challenges for suicide prevention research within the DoD setting. We have also learned that a change of leadership at inpatient psychiatric units may have an impact on implementation. In recent months, the WRNMMC inpatient psychiatric unit is focusing on a shorter length of stay for patients which makes it a challenge for our research team to deliver the study intervention to those randomized to the PACT condition.

This study is responsive to the critical mental health care needs of military service members by providing a targeted cognitive behavioral intervention for suicide ideation and behavior severe enough to warrant psychiatric hospitalization. The ultimate goal of the treatment is to prevent suicide and associated risk factors within a high risk group of the Armed Forces. Without adequate treatment, suicide related events leading to psychiatric hospitalization may result in costly utilization of military, VA, and civilian health and social services, a decrease in operational readiness and morale, human suffering, and eventual death.

Furthermore, this study is aligned with several critical research areas recognized by the US Research and Materiel Command: (1) reduction of the impact of mental disorders for the Armed Forces; (2) development of strategies to enhance mental health and well-being throughout service members' careers; (3) validation of effective psychotherapy interventions; (4) targeted evidence-based risk reduction methods for suicide behavior; (5) development of valid treatment related outcome measures and tracking systems; (6) reduction of barriers to care and appropriate linkage to healthcare services; and (7) special considerations for sub-populations with unique needs – for instance, those with combat trauma and/or Traumatic Brain Injury (TBI).

References

None.

Appendices

Appendix A – Data Tables
Appendix B – CONSORT

Table 1. Demographic Characteristics of Sample (N = 39)*¹

Demographic	Total (N = 39)	PACT+EUC (N = 20)	EUC (N = 19)
Age, mean (SD), years	29.5 (7.9) min: 19.0 max: 51.0	28.2 (6.9) min: 19.0 max: 44.0	30.8 (8.8) min: 19.0 max: 51.0
Admission Reason			
Suicidal ideation with history of suicidal attempt	16 (41.0)	9 (45.0)	7 (36.8)
Recent suicidal attempt	23 (59.0)	11 (55.0)	12 (63.2)
Site			
WRNMMC	28 (71.8)	15 (75.0)	13 (68.4)
Fort Belvoir	11 (28.2)	5 (25.0)	6 (31.6)
Gender			
Male	25 (64.1)	15 (75.0)	10 (64.1)
Female	14 (35.9)	2 (25.0)	9 (47.4)
Marital Status			
Single	12 (30.8)	6 (30.0)	6 (31.6)
Married	20 (51.3)	11 (55.0)	9 (47.4)
Cohabitating/Unmarried Partner	1 (2.6)	0	1 (5.3)
Annulled/Separated/Divorced/Widowed	6 (15.4)	3 (15.0)	3 (15.8)
Race			
American Indian/Alaska Native	2 (5.1)	2 (10.0)	0
Asian	2 (5.1)	2 (10.0)	0
Black/African-American	9 (23.1)	4 (20.0)	5 (26.3)
White/Caucasian	25 (64.1)	11 (55.0)	14 (73.7)
Two or more	1 (2.6)	1 (5.0)	0
Ethnicity			
Hispanic/Latino	8 (20.5)	6 (30.0)	2 (10.5)
Non-Hispanic/Latino	29 (74.4)	13 (65.0)	29 (74.4)
Unknown	2 (5.1)	1 (5.0)	1 (5.3)
Education			
High school diploma or equivalent	9 (23.1)	7 (35.0)	2 (10.5)
Some college, no degree	24 (61.5)	10 (50.0)	14 (73.7)
Higher studies	6 (15.4)	3 (15.0)	3 (15.8)
Branch of Military Service			
Army	17 (43.6)	8 (40.0)	9 (47.4)
Air Force	3 (7.7)	1 (5.0)	2 (10.5)
Navy	9 (23.1)	6 (30.0)	3 (15.8)
Marine Corps	9 (23.1)	5 (25.0)	4 (21.1)
Military Rank			
E1 - E4	16 (41.0)	9 (45.0)	7 (36.8)
E5 - E9	16 (41.0)	9 (45.0)	7 (36.8)
Warrant Officer (W1 - W5)	1 (2.6)	0	1 (5.3)
Officer (O1 - O10)	3 (7.7)	1 (5.0)	2 (10.5)
Civilian	2 (5.1)	1 (5.0)	1 (5.3)
Unknown	1 (2.6)	0	1 (5.3)

* Data presented as No. (%), except as noted

¹ Data as of February 2nd, 2015. A total of 91 participants were approached to participate in the study. Fifty-two participants declined or were excluded during the consent process or prior to randomisation.

Table 2. Clinical Characteristics of Sample (N = 39)*²

Assessment	Total (N = 39)	PACT+EUC (N = 20)	EUC (N = 19)
Scale For Suicide Ideation (Current Day)	4.3 (7.1) min: 0 max: 24	2.4 (5.8) min: 0 max: 24	6.3 (7.9) min: 0 max: 23
Scale For Suicide Ideation (Worst Day)	25.1 (7.3) min: 9 max: 38	24.2 (7.4) min: 10 max: 33	26.0 (7.3) min: 9 max: 38

* Data presented as Mean (SD), unless otherwise noted

Table 3. Baseline Symptomatology (N = 39)

	Total (N = 39)	PACT+EUC (N = 20)	EUC (N = 19)
Suicide Attempts			
None	0	0	0
Once	13 (33.3)	5 (25.0)	8 (42.1)
Twice or more	26 (66.7)	15 (75.0)	11 (57.9)

* Data presented as No. (%), except as noted

Table 4. Summary of Adverse Events (N = 10)

Type of Serious AE	Total (N = 10)	PACT+EUC (N = 6)	EUC (N = 4)
Expected but not related	9	5	4
Expected and possibly related	1	1	0
Expected and definitely related	0	0	0
Unexpected and not related	0	0	0
Unexpected and possibly related	0	0	0
Unexpected but definitely related	0	0	0

² Data as of February 2nd, 2015. A total of 91 participants were approached to participate in the study. Fifty-two participants declined or were excluded during the consent process or prior to randomisation.

Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram for PACT

